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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administrati

Dallas District
4040 North Central Expressv
Dallas, Texas 75204-3145

July 1, 2003

Ref: 2003-DAL-WL-13

**CERTIFIED MAIL**
**RETURN RECEIPT REQUESTED**

**WARNING LETTER**

Mr. William King, Owner
Gulf Tex Seafood
3410 Plum Tree Drive
Ellicott City, Maryland 21042

Dear Mr King:

On April 28 - May 2, 2003, the Food and Drug Administration (FDA) inspected your seafood processing facility, located at 826 25th Street, San Leon, Texas. We found that you have serious deviations from the Seafood Hazard Analysis and Critical Control Points (HACCP) regulations, Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). Accordingly, your cooked, ready-to-eat crabmeat is adulterated in that the crabmeat has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulations through links in FDA's Internet home page at http://www.fda.gov.

The deviations were as follows:

1. You must conduct, or have conducted for you, a hazard analysis to determine whether there are food safety hazards that are likely to occur, and you must have a HACCP plan to control any food safety hazards that are likely to occur to comply with 21 CFR 123.6(a) and (b). A food safety hazard is defined in 21 CFR Part 123.3(f) as any biological, chemical, or physical property that may cause a food to be unsafe for human consumption. However, your firm's HACCP plan for cooked, ready to eat crabmeat does not list, specifically at the receiving step in the plan, the food safety hazard of chemical

contaminants from the various bodies of water where the live crabs are harvested.

2. You must have a HACCP plan that, at a minimum, lists the critical limits that must be met in order to comply with 21 CFR 123.6(c)(3). A critical limit is defined in 21 CFR 123.3(c) as "the maximum or minimum value to which a physical, biological, or chemical parameter must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard." However, your firm's HACCP plan for cooked, ready to eat crabmeat does not list a critical limit related to the specific temperature of the production room for the [redacted] and [redacted] plan while processing is occurring. Since your firm does not process at a room temperature of 40° F or below, you must monitor the time in which the product is exposed to temperatures above refrigeration in order to control *Listeria monocytogenes* and other pathogens. Additionally, the plan lists a critical limit, "More than [redacted] exposure," at the picking and packing critical control point that is not adequate to control pathogen growth. Furthermore, the critical limit for the refrigeration critical control point allowing temperatures of [redacted]° F for all other products, except whole cooked or backed cooked crabs, is not sufficient to control *Listeria monocytogenes* and other pathogens. The critical limit for controlling these pathogens at the refrigeration critical control point is a maximum temperature of 40 ° F.

3. You must have a HACCP plan that lists monitoring procedures for each critical control point to comply with 21 CFR 123.6(c)(4). Your HACCP plan for cooked crabmeat lists a monitoring procedure of a [redacted] check on temperature and time at the cooking critical control point to control *Listeria monocytogenes* and other pathogens. However, your equipment does not have a temperature recording device or combined time/temperature recording device in order to monitor this critical control point.

4. You must fully implement the monitoring procedures listed in your HACCP plan to comply with 21 CFR 123.6(b). However, your firm did not follow the monitoring procedure of recording the temperature at the time the crab backing and rinse step began, as listed in your HACCP plan. For example, on April 28, 2003, the time was recorded when the backed crabs were placed in the cooler, and not at the time the actual backing and rinsing process began. Additionally, the refrigeration critical control point requires the temperature of the cooler to be checked every [redacted] while working. On April 29, 2003, the temperature was not checked every [redacted] as required by the plan.

5. Your HACCP plan must provide for a recordkeeping system that documents the monitoring of the critical control points specified in the plan to comply with 21 CFR 123.9. All processing or other information must be entered concurrent with the activity or when the observation was made. On April 28, 2003, the Daily Cook Log had the temperature of [redacted]° F pre-printed on it, and did not reflect the actual cook temperature of [redacted] ° F.

6. You must take an appropriate corrective action when a deviation from a critical limit occurs to comply with 21 CFR 123.7(a). However, your firm did not take corrective action to control *Listeria monocytogenes* or other pathogens when your process for cooked crabmeat deviated from your critical limit at the refrigeration critical control point. On April 29, 2003, your final product cooler temperature was 45°F while your critical limit is [redacted]°F.

7. You must adequately monitor sanitation conditions and practices during processing to comply with 21 CFR 123.11(b). However, your firm did not monitor the prevention of cross-contamination from insanitary objects to food, as evidenced by ice being stored inside gray barrels used for crab waste; barrels used in the processing of crabs were not washed, rinsed or sanitized prior to being used in the backing operation; and rakes used to move cooked crabs during the backing operation were found to have crab residue on the handles from previous operations.

In addition, the investigator documented numerous insanitary conditions that cause the crabmeat you manufacture to be adulterated within the meaning of Section 402(a)(4) of the Act.

The deviations were as follows:

8. Employees working in direct contact with food and food-contact surfaces did not take necessary precautions to protect against contamination of those items with microorganisms or foreign substances. For example, employees were observed chewing gum in areas where food is exposed and equipment or utensils are washed [21 CFR 110.10(b)(8)].

9. Floors in the live crab cooler, crab cooking room, and backing room were not adequately cleaned prior to production as seen by black mold-like material on the floor in each room. The walls in the backing room were unclean and contained crab residue from previous day production [21 CFR 110.20(b)(4)].

You should take prompt action to correct these violations and prevent their recurrence. Failure to promptly do so may result in regulatory action without further notice, such as seizure or injunction.

We are aware that you made a verbal commitment to correct the deviations during the inspection. Please respond in writing within 15 working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You should include in your response documentation such as copies of your revised HACCP plan and temperature monitoring records or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations, and the Good Manufacturing Practice regulations, 21 CFR 110. You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the U.S. Food and Drug Administration, Attention: Reynaldo R. Rodriguez, Jr., Director, Compliance Branch, at the above letterhead address. If you have questions regarding any issue in this letter, please contact Mr. Rodriguez at (214) 253-5215.

Sincerely,

Michael A. Chappell
District Director